

REMARKS

Claims 14-24 have been canceled without prejudice or disclaimer. Claims 25-38 have been added and therefore are pending in the present application. Claims 25-38 are supported throughout the specification, including the original claims. In addition, the phrase "at least one thermostable polypeptide having xylanase activity and which is a family 10 glycoside hydrolase" is supported by page 4, lines 36-37 of the specification.

The specification has been amended to use the numbering of the amino acid positions shown in the Sequence Listing submitted on January 18, 2005.

An abstract of the disclosure has been added as a separate page, as requested by the Examiner.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Restriction Requirement

The Office maintained the restriction requirement finding "Applicant's argument [that] claims are linked by special technical feature is not persuasive because Hong et al. ... disclose a polynucleotide sequence with 99% sequence homology to SEQ ID NO: 1 and 17 and encoding a polypeptide with endoglucanase activity that has 100% sequence homology to SEQ ID NO: 2 and 18. Therefore the technical features linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2." This is respectfully traversed.

Applicants' claimed inventions are directed to compositions comprising at least one thermostable polypeptide having xylanase activity and at least one thermostable polypeptide having endoglucanase activity, as well as methods of using such compositions. Since Hong et al. do not disclose Applicants' compositions, the claims are linked as to form a single general inventive concept.

For the foregoing reasons, Applicants submit that the restriction requirement is improper. Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

II. The Rejection of Claims 16 and 17 under 35 U.S.C. 112

Claims 16 and 17 are rejected under 35 U.S.C. 112 as being indefinite. Specifically, the Office objected to the phrase "% identity," the lack of hybridization conditions, the phrase "a complementary strand," and the phrase "derived from."

Claims 14-24 have been rewritten as claims 25-38 to address this rejection. Applicants therefore submit that this rejection has been overcome.

III. The Rejection of Claims 14-21 under 35 U.S.C. 112

Claims 14-21 are rejected under 35 U.S.C. 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

As set forth in Federal Circuit decisions, a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). In *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613, the Federal Circuit held that, "It is not correct ... that all functional descriptions of genetic material fail to meet the written description requirement."

The claimed invention is drawn to compositions comprising at least one thermostable polypeptide having xylanase activity and which is a family 10 glycoside hydrolase, and at least one thermostable polypeptide having endoglucanase activity. The polypeptide having endoglucanase activity is defined by structure, namely, by (a) having an amino acid sequence which has at least 95% sequence identity to two specific sequences, (b) being encoded by a nucleic acid sequence which hybridizes under specified conditions with specified sequences, or (c) being a fragment of (a) or (b) that has endoglucanase activity. Thus, the specification fully describes the compositions of the present invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 14-21 under 35 U.S.C. 112

Claims 14-21 are rejected under 35 U.S.C. 112 "because the specification, while being enabling for a composition comprising an endoglucanase consisting of amino acid residues 30-305 of SEQ ID NO: 2 or the mature polypeptide amino acid residues 1-303 of SEQ ID NO: 18 and ... a xylanase of SEQ ID NO: 2 encoded by a polynucleotide of SEQ ID NO: 1 ..., does not reasonably provide enablement for any composition comprising the elected thermostable enzymes having xylanase and endoglucanase activities...." This rejection is respectfully traversed.

It is well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

Applicants submit that the specification complies with the enablement requirement.

The claimed invention is drawn to compositions comprising a thermostable endoglucanase and a thermostable xylanase of family 10. The endoglucanases are structurally similar because they are encoded by DNA sequences which hybridize under specified stringency conditions with SEQ ID NO: 1 or 17, or have amino acid sequences which a high level of identity with SEQ ID NO: 2 or 18. The xylanases also are structurally similar because they belong to family 10. Thus, the specification provides a precise definition of the claimed polypeptides. Furthermore, the specification contains an extensive disclosure of techniques which are well known in the art and indeed routine for persons of ordinary skill in the art for identifying other endoglucanases and xylanases.

We draw the Examiner's attention to *In re Angstadt*, 190 U.S.P.Q. 214 (C.C.P.A. 1976). In *Angstadt*, the claimed process of preparing hydroperoxides used a metal salt complex as a catalyst. The specification disclosed catalysts that worked and some that gave little or no yield of hydroperoxides. The claims were rejected for lack of enablement, specifically as requiring undue experimentation to find useful catalysts. This rejection was reversed by the CCPA.

In holding that the claims did satisfy 35 USC 112, the Court observed, 190 U.S.P.Q. at 218:

We cannot agree with the board that appellants' disclosure is not sufficient to enable one of ordinary skill in the art to practice the invention without undue experimentation. We note that many chemical processes, and catalytic processes particularly, are unpredictable, [citation omitted] and that the scope of enablement varies inversely with the degree of unpredictability involved, [citation omitted]. That this particular process is unpredictable is demonstrated further by appellants in their specification. Appellants have disclosed forty examples; one of these examples yields no hydroperoxides in the final product. Also, appellants

have expressly indicated in their specification that some of these organometallic complex catalysts 'yield *** no hydroperoxides in the final product.'

Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with 'thousands' of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid 'literal' infringement of such claims by merely finding another analogous catalyst complex which could be used in 'forming hydroperoxides.'

The Court, 190 USPQ at 218, recognized that some experimentation might be necessary for the skilled worker to select non-exemplified catalysts for use:

Appellants have, in effect, provided those skilled in this art with a large but finite list of transition metal salts from which to choose in preparing such a complex catalyst. Appellants have actually carried out 40 runs using various transition metal salts and hexaalkylphosphoramides. If one skilled in this art wished to make and use a transition metal salt other than those disclosed in appellants' 40 runs, he would merely read appellants' specification for directions how to make and use the catalyst complex to oxidize the alkylaromatic hydrocarbons, and could then determine whether hydroperoxides are, in fact, formed. The process discovered by appellants is not complicated, and there is no indication that special equipment or unusual reaction conditions must be provided when practicing the invention. One skilled in this art would merely have to substitute the correct mass of a transition metal salt for the transition metal salts disclosed in appellants' 40 runs. Thus, we have no basis for concluding that persons skilled in this art, armed with the specification and its 40 working examples, would not easily be able to determine which catalyst complexes within the scope of the claims work to produce hydroperoxides and which do not.

However, while some experimentation might be necessary, as long as the experimentation was not "undue experimentation," the claims would not violate 35 USC 112, *Angstadt, Id.*

Since appellants have supplied the list of catalysts and have taught how to make and how to use them, we believe that the experimentation required to determine which catalysts will produce hydroperoxides would not be undue and certainly

would not 'require ingenuity beyond that to be expected of one of ordinary skill in the art.' (Emphasis added).

As in *Angstadt*, the present application describes endoglucanases and xylanases for use in the compositions of the present invention. While some experimentation might be necessary to identify other non-exemplified endoglucanases and xylanases, such experimentation would require carrying out a simple process without special equipment or unusual reaction conditions, as in *Angstadt*. This experimentation, if required, "would not be undue and certainly would not 'require ingenuity beyond that expected of one of ordinary skill in the art.'" (*Angstadt*, 190 U.S.P.Q. at 218). Certainly, there is no evidence of record to the contrary.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

V. The Rejection of Claim 16 under 35 U.S.C. 112

Claim 16 is rejected under 35 U.S.C. 112 as failing to comply with the enablement requirement because Applicants have not provided the assurances required under 35 C.F.R. 1.801 – 1.809 for the biological material recited in claim 16.

As requested by the Examiner, Applicants confirm that biological material recited in claim 16 was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) under the Budapest Treaty and assigned accession number DSMZ 14541. All restrictions on the availability to the public of said deposited material will be irrevocably removed upon the granting of the U.S. patent. Said deposit will be maintained for (a) thirty years, (b) at least five years after the most recent request for the furnishing of a sample of the deposit is received by the depository, or (c) the enforceable life of the U.S. patent granted from this application, whichever is longest. If the deposited material becomes inviable during the above term, the deposited material will be replaced.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. The Rejection of Claims 14-21 under 35 U.S.C. 103

Claims 14-21 are rejected under 35 U.S.C. 103 as being unpatentable over Hong et al. (PUBMED, Gene Accession No. AY055121), Hansen et al. (WO 96/23062 and U.S. Patent No. 5,817,500), Fagerstrom et al. (U.S. Patent No. 5,922,579), and Paloheimo et al. (U.S. Patent No. 6,228,629). This rejection is respectfully traversed.

Hong et al. disclose a polypeptide with endoglucanase activity that has an amino acid sequence which is 99.4% identical to SEQ ID NO: 2 and 18. However, Hong et al. do not teach or suggest compositions comprising an endoglucanase and a xylanase.

Hansen et al. disclose a xylanase derived from *Thermomyces lanuginosus* and its use in animal feed.

Paloheimo et al. disclose three xylanases from *Chaetomium thermophilum* (encoded by xlnA, xlnB, and xlnC). Paloheimo et al also disclose the construction of fusion proteins thereof with various enzymes including endoglucanases.

Fagerstrom et al. also disclose a number of xylanases derived from *Chaetomium thermophilum* and the use thereof in the bleaching of plant pulp and in feed and baking applications. Fagerstrom et al. also propose blends of the xylanases with other enzymes such as endoglucanases.

However, from the CAZy internet site (www.cazy.org/fam/GH11.html), the xylanases described in Hansen et al., Paloheimo et al., and Fagerstrom et al. are not xylanases of glycoside hydrolase family 10.

Applicants therefore submit that the cited references do not teach or suggest the compositions of the invention.

Moreover, none of the cited references suggest that the compositions of the present invention improve the nutritional value of animal feed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

VII. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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